IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ADVANCED CARDIOVASCULAR SYSTEMS, INC. and GUIDANT SALES CORPORATION,

Plaintiffs,

v.

MEDTRONIC VASCULAR, INC. and MEDTRONIC USA, INC.,

Defendants.

C.A. No. 98-80 (SLR)
(Consolidated with Civil Action No. 98-314 (SLR) and Civil Action No. 98-316 (SLR))

REDACTED
MEDTRONIC'S SUBMISSION REGARDING THE TRIAL OF DAMAGES AND WILLFULNESS

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INTRODUCTION

Pursuant to the Court's instructions at the March 2, 2005 hearing on this matter, Medtronic submits this brief addressing the following five issues: (1) why the existing stay on damages and willfulness should remain in effect; (2) the nature and scope of the damages and willfulness discovery that would have to be conducted if the stay is lifted; (3) an overview of the evidence Medtronic intends to present at the damages and willfulness trial; (4) an estimate of the amount of time necessary to try damages and willfulness; and (5) why a continued stay on damages and willfulness will not have any impact on the liability issues.

I. DAMAGES AND WILLFULNESS SHOULD REMAIN STAYED PENDING RESOLUTION OF LIABILITY ISSUES IN THIS AND RELATED CASES THAT MAY IMPACT DAMAGES AND WILLFULNESS.

As the Court is well aware, the "stent wars" involve a myriad of patent infringement suits that have been brought by the major players in the stent industry against one another and involve a number of different patents claiming various aspects of "first generation" and "second generation" stent technology and beyond.[1] As the Court is also aware, none of these cases has been fully and finally adjudicated, and, as a result,

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[1] The cases pending in this district alone include, among others, *Cordis v. Medtronic (AVE)*, C.A. No. 97-550 (Palmaz patents); *Cordis v. Medtronic*, C.A. No. 00-886 (Palmaz patents); *Cordis v. Boston Scientific*, C.A. No. 03-027 (Palmaz patents); *Boston Scientific Scimed v. Cordis*, C.A. No. 03-283 (BSC patents); *Boston Scientific Scimed v. Cordis*, C.A. No. 03-1138 (BSC patents); *Medtronic v. ACS*, C.A. No. 98-80 (Boneau patents); *Medtronic v. BSC*, C.A. No. 98-478 (Boneau patents); *ACS v. Medtronic*, C.A. Nos. 98-80, 98-314, and 98-316 (Lau patents); *Medtronic v. Cordis*, C.A. No. 03-402 (Boneau patents); and *Medtronic v. Boston Scientific*, C.A. No. 04-034 (Boneau patents).

there is still significant uncertainty concerning who in the end will be liable to whom and for what conduct. [redacted] It therefore makes sense to keep the current stay on damages and willfulness in place until at least some of these uncertainties can be fully resolved. ACS would be hard-pressed to contend otherwise because this is the exact same position that ACS itself asserted in the past.

The following facts (among others) justify maintaining the stay.

A. The Medtronic/Cordis Arbitration–Which Was The Basis On Which ACS Moved, And The Court Granted, A Stay In This Case–Has Not Yet Been Completed.

In the 03-402 case, Medtronic alleged that Cordis's stents infringed Medtronic's Boneau patents. Cordis argued that it could not be held liable for infringement because it has a license to the Boneau patents. In May 2004, the Court stayed that case pending the resolution of an arbitration of Cordis's license defense (D.I. 167 (03-402 case)). Shortly afterward, ACS moved the Court in the 98-80, 98-314, and 98-316 cases to stay *both* Medtronic's suit against ACS for infringement of the Boneau patents (the 98-80 case) *and* ACS's suit against Medtronic for infringement of the Lau patents (the 98-80, 98-314, and 98-316 cases) pending the outcome of the Medtronic/Cordis arbitration (D.I. 371 (98-80 case)). ACS argued (among other things) that the outcome of the arbitration could impact damages (D.I. 372 at 2 and 5 (98-80 case)). In August 2004, the Court granted ACS's motion in part and stayed damages and willfulness in *both* cases pending completion of the Cordis arbitration (D.I. 444 at 3-4 (98-80 case)).

The Medtronic/Cordis arbitration has not been completed, though it is now set for hearing in November 2005. Thus, the very event that ACS argued warranted the stay has not taken place and will not take place for some time. Moreover, depending on how the Court rules on Medtronic's motion to stay litigation of the 00-886 case pending arbitration,[2] that panel also may decide whether Medtronic has a license to the Palmaz patents with respect to certain Medtronic products. As such, the stay should remain in effect at least until the Medtronic/Cordis arbitration is resolved.

B. Medtronic's Appeal On Liability In This Case May Significantly Impact ACS's Damages And Willfulness Claims, And Could Ultimately Render A Damages And Willfulness Trial Unnecessary.

The Court has already commented that claim construction in this case presented very close issues and that the Court is uncertain as to how the Federal Circuit will resolve those issues on appeal (2/16/05 Tr. at 1711:8-19 ("I have to admit, I think both parties stated absolutely appropriate constructions in this case. . . . I don't have a clue which way the Federal Circuit will go on this.")). Thus, it is possible the Federal Circuit will reverse at least some aspects of the Court's claim construction rulings and remand for a retrial of liability. Medtronic also is moving for a new trial. That being the case, it certainly will not serve the interests of efficiency and economy for the Court and the parties to spend significant time and resources engaging in fact and expert discovery and conducting a full blown trial on damages and willfulness. Indeed, if Medtronic

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[2] The Court recently issued an Order indicating that it is in the process of reviewing its prior Order on the topic and that it will issue a decision in due course (D.I. 112).

prevails on appeal or upon retrial, any interim trial on damages and willfulness will have been a waste of time and resources. Thus, the stay should remain in effect until Medtronic's appeal of the liability issues in this case is resolved.

C. Medtronic's Appeal On The Boneau Patents May Impact ACS's Damages Claim In This Case.

[redacted]

If the Court's order granting ACS's motion for partial summary judgment that the ACS Multilink stents do not infringe the Medtronic Boneau patents is reversed on appeal, and Medtronic is able to prove that the Multilink stents infringe those Boneau patents, then ACS would not be able to collect any lost profits damages at all in its case against Medtronic. That is because ACS could not prove that it had the lawful ability to make and sell any of its Multilink stents, let alone the ability to make and sell more of those stents. *See Micro Motion, Inc. v. Kane Steel Co.,* 894 F.2d 1318, 1322 (Fed. Cir.

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[3] These numbers presumably will go up when financial information after March 2004 is included.

1990) (a source of supply cannot be considered in a lost profits analysis if that source is itself an infringer). It certainly would not serve the interests of efficiency and economy for the Court and the parties to expend an enormous amount of time and resources engaging in discovery (and discovery disputes), motion practice, and conducting a full blown damages and willfulness trial when the verdict resulting from such a trial may have to be set aside and retried all over again if Medtronic is successful on its appeal in the 98-80 case. Thus, the stay should remain in effect until Medtronic's appeal of the liability issues in its suit against ACS is fully resolved.

It bears emphasis that ACS previously argued for practically the same approach. In the 98-478 case, in July 2004, BSC moved to bifurcate and stay all damages issues pending the final resolution, "including appeals," of all of the many stent cases (D.I. 231 (98-478 case)). In its motion, BSC noted that there were at least nine stent cases pending before the Court involving Medtronic, Cordis, ACS, and BSC. BSC argued that "no one" could determine the proper measure of damages in any of these cases until all of the liability issues were finally determined, including the resolution of all appeals. BSC argued that because all of the parties were "large multinational companies with substantial financial resources, there would be no prejudice to stay damages issues until "all liability determinations become final" (D.I. 232 at 2). In August 2004, ACS joined BSC's motion, stating: "ACS requests that the Court bifurcate trial of the above captioned case into a liability phase and a damages phase, with the

damages phase taking place only after the Court has resolved all issues as to liability in this and in the other pending stent cases." (emphasis added) (D.I. 393 (98-80 case)).[4]

D. Cordis's Ongoing Lawsuits Against Medtronic For Infringement Of The Palmaz Patents May Significantly Impact Damages In This Case, And May Even Warrant Consolidating The Cordis And ACS Cases For Purposes Of Trying Damages.

As the Court is aware, in the 97-550 and 00-886 cases, Cordis has sued Medtronic for infringing the Palmaz patents. The Court entered judgment of liability in the 97-550 case against Medtronic on March 31, 2005, and the 00-886 case is still ongoing. It is crucial to note that in those two cases, Cordis has accused some of the same Medtronic stents as ACS has accused in this case. It is just as critical to note that Cordis and ACS are both seeking lost profits and reasonable royalty damages on some of the same accused Medtronic stents. This raises a host of significant damages issues.

Under a lost profits analysis, a patentholder can seek to recover its lost profits on the accused infringer's sales it would have made "but for" the alleged infringement. *BIC Leisure Prods., Inc. v. Windsurfing Int'l, Inc.*, 1 F.3d 1214, 1218 (Fed. Cir. 1993). In the first trial of the 97-550 case, Cordis's damages expert testified that from 1998 to 1999, Cordis would have made about 80% of Medtronic's accused sales[5] (Exh. A (Trial Tr.) at 2908-09; 2938; 2978-79; 3594; 3596-97; 3610). [redacted]

[redacted]

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4 These motions were withdrawn as moot after the Court issued its Order bifurcating damages pending the Cordis arbitration.

5 [redacted]

[redacted]

Moreover, under a reasonable royalty analysis, a royalty rate is determined by the amount that a person in a "hypothetical negotiation" would have been willing to pay as a royalty and yet be able to make a reasonable profit. *Trans-World Mfg. Corp. v. Al Nyman & Sons, Inc.*, 750 F.2d 1552, 1568 (Fed. Cir. 1984). Here, Cordis's and ACS's separate patent claims against some of the same products may lead to inconsistent royalty determinations in the Cordis cases and this case. [redacted]

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6 [redacted]

7 [redacted]

[redacted]

[redacted] And, during the hypothetical negotiations, would Medtronic have argued for a reduced royalty rate on both the Cordis Palmaz patents and the ACS Lau patents so that it could make and sell its stents at a reasonable profit as the law contemplates? These complex questions are compounded by the fact that Johnson & Johnson, the parent of Cordis, recently inked a deal to acquire Guidant Corporation, the parent of ACS (Exh. C (Guidant webpage)). Thus, if that acquisition goes through, Johnson & Johnson will be in a position in these lawsuits to essentially seek a double recovery from Medtronic.

Moreover, as this Court is aware, Medtronic believes that it has the right to arbitrate whether it has a license to the Cordis patents with respect to certain products. The resolution of this issue may also impact the reasonable royalty analysis.

These considerations warrant maintaining the stay in this case until liability in all of these cases is fully resolved, just as ACS had previously proposed. After those issues are fully resolved, to the extent there is even a need for a damages trial, consideration should be given to consolidating the two Cordis cases and this case for purposes of determining damages and willfulness. This proposal will save time and resources and will reduce the chances of inconsistent judgments and having to retry damages later on down the road.

E. The Existence Of So Many Unresolved Cases And Issues Has Made It Practically Impossible To Fully Assess Alternative Non-Infringing Products—An Issue That May Have A Significant Impact On ACS's Damages Claim.

At the March 2 hearing, the Court noted that the issue of alternative non-infringing products is a significant damages-related issue and that determining such products is difficult given the procedural posture of the various stent cases (03/02/05 Tr. at 10:5-8 ("We've got so much going on. And it is hard to keep track of and hard to tell whether there are any non-infringing alternatives to any patents at this point.")). The Court was correct on both points. First, the existence of actual or potential alternative non-infringing products may have an enormous impact on both the lost profits and the reasonable royalty analysis. *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341, 1353-55 (Fed. Cir. 1999); *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970). Second, to date, it has been practically impossible for Medtronic and its technical and damages experts to fully assess alternative non-infringing products.

For example, all of the asserted claims of the four ACS patents require "cylindrical elements," which the Court construed in pertinent part to mean "a radially expandable segment of a stent having a *longitudinal length less than its diameter* with a circumferential undulating pattern" (D.I. 542 at 2-3). In its renewed JMOL filed concurrently herewith, Medtronic shows that, to satisfy the requirement of a longitudinally flexible stent (which the Court said must "facilitate delivery" to the body lumens), the longitudinal length of the cylindrical elements must be less than their diameter in the crimped state. With the exception of Medtronic's S7 and Driver stents,

however, ACS failed to prove that Medtronic's accused stents have cylindrical elements with a longitudinal length less than their diameter in the crimped state.

The Court's resolution of Medtronic's JMOL may shed some light on the issue of alternative non-infringing products. The Federal Circuit's resolution of many of the liability issues in all of the stent cases may further impact that issue. As a limited example, Medtronic may be able to argue that a design around was available by making a stent in which the longitudinal length of the sinusoidal rings was greater than their diameter. This may eliminate ACS's ability to recover any lost profits and may significantly reduce ACS's claim of reasonable royalty damages. *Grain Processing*, 185 F.3d at 1356 ("[W]ith proper economic proof of availability, . . . an acceptable substitute not on the market during the infringement may nonetheless become part of the lost profits calculus and therefore limit or preclude those damages").

[redacted] Therefore, the issue of alternative non-infringing products is a significant issue that may have an equally significant impact on ACS's damages claims in this case. For that reason, the stay should remain in effect until all of these cases are resolved and Medtronic is able to fully assess the issue of alternative non-infringing products.

II. SIGNIFICANT FACT AND EXPERT DISCOVERY STILL NEEDS TO BE CONDUCTED RELATED TO THE DAMAGES AND WILLFULNESS ISSUES.

With respect to damages, at the March 2 hearing, the Court instructed the parties to exchange updated sales and cost information, exchange amended expert reports based on the updated sales and cost information, and schedule the damages experts'

depositions (D.I. 642 at 25). Although ACS produced its updated sales information, it initially resisted producing its updated cost information and providing updated expert reports. Although the parties recently agreed to a schedule for exchanging amended expert reports, that schedule may now be delayed because ACS has not yet produced its updated cost information (and agreed to do so only within the last day or so).

As Medtronic argued in Section I, *supra*, Medtronic believes that it will be premature to go forward with damages proceedings at this time in light of, *inter alia*, the lack of finality on non-infringing substitutes. If, however, the Court were to lift the stay on the damages phase of the case, Medtronic would file a motion for leave to permit its technical and damages experts to supplement their reports to include their opinions that Medtronic could have designed around ACS's patents-in-suit.[8] This would likely require some additional fact discovery (to address Medtronic's manufacturing and design capabilities) as well as expert discovery. The exact scope and nature of this testimony, furthermore, may be impacted by the Court's ruling on Medtronic's JMOL motion (and, possibly, the new trial motion), filed concurrently with this submission.

To date, the parties have not engaged in any significant discovery focused specifically on willfulness, primarily because the parties had not yet agreed to a date for the election on whether to waive the attorney-client privilege with respect to opinions of counsel. The Court has, in the past, been justifiably hesitant to force such an election prematurely; and not forcing Medtronic to decide whether to waive the privilege until the

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[8] Medtronic's experts could not have reasonably anticipated this issue earlier because the Court stayed the damages case in August 2004 and their opinions would be based on the Court's claim constructions which issued in January 2005, nearly five months later.

matter of liability has been definitively resolved remains in and of itself ample justification for delaying proceedings on damages and willfulness.

If Medtronic is put to an election and decides to waive its attorney-client privilege, the parties presumably would have to schedule the depositions of Medtronic's opinion counsel and also current or former Medtronic executives who will testify concerning Medtronic's reliance on the opinion(s) of counsel. Further, irrespective of whether Medtronic waives the privilege, in view of significant changes in the law governing the waiver of attorney-client privilege (*see Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337 (Fed. Cir. 2004)) Medtronic would need to supplement the evidence upon which it would rely in defending against a charge of willfulness. For example, the parties will likely need discovery on the other willfulness factors, including that Medtronic did not deliberately copy ACS's patented design; Medtronic did not conceal its allegedly infringing activity; Medtronic did not believe that any of its defenses were frivolous; Medtronic allegedly infringing activity was not designed to injure ACS; and Medtronic formed a good faith belief as to invalidity or non-infringement (apart from the advice of counsel). *See Read Corp. v. Portec, Inc.*, 970 F.2d 816, 826-29 (Fed. Cir. 1992).

Given that the parties' various fact and expert witnesses reside throughout the country from New York to California, completing all of this discovery will involve significant time and expense.

III. THE PARTIES WILL HAVE TO PRESENT A GREAT DEAL OF EVIDENCE, INCLUDING EVIDENCE THAT OVERLAPS WITH THE EVIDENCE THAT WAS PRESENTED DURING THE LIABILITY TRIAL, DURING A TRIAL ON DAMAGES AND WILLFULNESS.

In a patent case, when liability is tried separately from damages and willfulness before separate juries, the damages and willfulness trial cannot be conducted in an "evidentiary vacuum." *See THK Am., Inc. v. NSK Co.*, 151 F.R.D. 625, 630 (N.D. Ill. 1993). During the damages and willfulness trial, the jury has to be educated as to the technology at issue, the patents in suit, the claims and the claim constructions, the relevant industry and market conditions, the embodying and accused products, and the parties' respective positions on both infringement and invalidity. *See id.* Although evidence on these issues would appear to relate only to liability issues, that is not the case; such evidence also bears significantly on issues of damages and willfulness. *See id.*; *Ryco, Inc. v. Ag-Bag Corp.*, 857 F.2d 1418, 427-28 (Fed. Cir. 1988) (lost profits analysis requires evidence related to market demand); *Georgia-Pacific,* 318 F. Supp. at 1120 (reasonable royalty analysis requires evidence related to nature and advantages of patented invention); *Read Corp.*, 970 F.2d at 826-29 (willfulness analysis requires evidence of whether the defendant had a good faith basis to believe that the patents in suit were not infringed or invalid). Only then will the jury be in a position to understand the additional evidence that relates even more directly to both damages and willfulness, such as testimony from the parties' financial personnel and damages experts and the parties' witnesses on the various willfulness factors.

In this case in particular, as set forth in its new trial motion, Medtronic believes that it has been greatly prejudiced because, if damages and willfulness are heard

now, the jury that will decide these issues will be different from the jury that heard the liability issues. The new jury will not have the same appreciation for how close the claim construction issues were, how the jury heard evidence regarding both proposed constructions, and how the claim construction issue was ultimately resolved by the Court in ACS's favor. Medtronic was prejudiced once by having claim construction played out before the jury. Medtronic submits that it will be prejudiced once again by having a different jury decide willfulness. After a finding of liability, it is naturally very difficult to recreate that evidence for a new jury.

Notwithstanding these concerns, with a stay in place almost nine months now, Medtronic has not come anywhere near completing its preparation for a trial on damages and willfulness. Even so, Medtronic at this point expects that it would have to call at least the following witnesses in a damages/willfulness trial:

- Medtronic's expert Dr. David Pearle on the background of the technology;
- Michael Boneau on the background of the technology and Medtronic's good faith belief that ACS's Lau patents are invalid;
- Jeff Allen on the background of the technology and Medtronic's good faith belief that ACS's Lau patents are not infringed, not willfully infringed, and are invalid;
- Medtronic's executives on Medtronic's ability to design around ACS's Lau patents;
- Medtronic's expert Dr. Raymond Vito on Medtronic's good faith belief that ACS's Lau patents are not infringed;

- Medtronic's expert Dr. Sunil Saigal on Medtronic's good faith belief that ACS's Lau patents are invalid;

- Medtronic's technical expert on Medtronic's ability to design around the ACS Lau patents;

- Medtronic's opinion counsel on Medtronic's good faith belief that ACS's Lau patents are not infringed and are invalid (assuming Medtronic waives the privilege);

- Medtronic's executives who relied on the opinion of counsel on Medtronic's good faith belief that ACS's Lau patents are not infringed and are invalid (assuming Medtronic waives the privilege);

- Several of ACS's personnel (by videotaped deposition) on Medtronic's good faith belief that ACS's Lau patents are invalid;

- Medtronic's sales and marketing personnel on market data and Medtronic's financial information; and

- Medtronic's damages expert Dr. Michael Keeley.

Moreover, it would not be surprising if ACS had to call many of the same witnesses it called during the liability trial, as well as its two damages experts, Dr. Sharon Oster and Dr. Ashley Stevens.

IV. A TRIAL ON DAMAGES AND WILLFULNESS WOULD REQUIRE AT LEAST TWO FULL WEEKS OF COURT TIME, IF NOT MORE.

Both the question of when the Court could proceed with a damages trial and the question of how long such a trial would take is difficult to answer with certainty before the Court addresses several threshold issues: first, there is the possibility of

additional fact and expert discovery (fact and expert discovery on non-infringing alternatives and with respect to the evidence upon which Medtronic would rely in defending against a charge of willfulness). Second, there are the motions for judgment as a matter of law and new trial filed with this submission. In addition, Medtronic filed two-damages related motions for summary judgment, one going to ACS's lost profits claim and the other going to the amount of offset that Medtronic is entitled to based on an amount Medtronic paid to ACS based on an arbitration in an earlier case (D.I. 413 & 417).[9]

As discussed above, a trial on damages and willfulness will require that the parties go over much of the same ground that they did during the trial on the liability issues, and then introduce additional evidence that relates solely to damages and willfulness. The Court will recall that the trial on the liability issues in this case lasted almost two full weeks with each side allotted twenty hours. It is difficult to imagine that a trial on damages and willfulness could be completed in less than that. Indeed, the Court will recall from the original trial in the 97-550 case between Cordis and Medtronic, it took the parties a full week to try the issue of damages alone (not also willfulness) before the same jury that also heard the liability issues.

[redacted]

Medtronic respectfully submits that both parties should be given the opportunity to present all of their evidence and arguments.

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[9] After the damages case was stayed, these motions were withdrawn from the Court's docket without prejudice (D.I. 450). Medtronic intends to refile these motions and would hope to have them resolved before trial.

V. A CONTINUED STAY ON DAMAGES AND WILLFULNESS WILL NOT IMPACT THE LIABILITY ISSUES THAT HAVE ALREADY BEEN TRIED.

At the close of ACS's evidence in this case, Medtronic asked the Court to enter a JMOL of non-infringement because ACS had failed to show that Medtronic made, used, sold or offered for sale any of the accused stents *during the terms of the ACS patents*, as plainly required under 35 U.S.C. §271. At the time, ACS argued that the missing evidence "goes to damages," and notwithstanding that it had the opportunity to do so, ACS declined to supplement its proof for purposes of the liability trial. Based on the record before it, the Court denied Medtronic's JMOL motion.

During the March 2 hearing, the Court said it might delay entering judgment on liability (or certifying such judgment for appeal) and proceed immediately with a damages trial. The Court suggested this might allow ACS to present evidence on the timing of Medtronic's sales before liability is presented to the Federal Circuit. Respectfully, Medtronic believes these concerns should not influence the decision of whether and when to proceed to a full-blown trial on damages and willfulness.

In its renewed JMOL motion, filed with this submission, Medtronic argues that judgment should be entered against ACS without further proceedings because ACS failed to establish a fundamental element of its liability case. The jury's finding of infringement must stand or fall on the evidentiary record that was before it. Nothing the Court or ACS does now will alter that conclusion. ACS may argue, for example, that it should be permitted to submit a written offer of proof concerning the additional evidence that it would hope to submit in a subsequent proceeding (to permit ACS to detail its expected evidence without wasting the Court's and the parties' resources). Medtronic

would urge the Court to reject even this sort of approach so that the parties can have the issue heard by the appellate court as expeditiously as possible. Moreover, there can be little question but that ACS's failure of proof provides no justification for holding now the full-blown damages trial that ACS seeks.

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462331

CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on April 27, 2005 I electronically filed the foregoing with the Clerk of the Court using CM/ECF which will send notification of such filing to the following:

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